REMARKS

Summary of Changes Made

By this Amendment, claims 4, 11 and 18 each have been amended to delete the first instance of the compound "polyethylene oxide", which was inadvertently repeated twice in each claim. No claims have been canceled, and no new matter has been added to the application. Thus, claims 1-21 remain pending.

Claim Rejections - 35 U.S.C. §102

In the prior Office Action, the Examiner rejected claims 1-3, 5-10, 12-17 and 19-21 under 35 U.S.C. §102(b) as being anticipated by Subramaniam et al., U.S. Pat. No. 5,874,029. For the reasons set forth herein, applicants respectfully request reconsideration of the rejection.

Subramaniam et al. is directed to a method and an apparatus for producing microparticles and nanoparticles using a supercritical anti-solvent process. In accordance with the teachings of Subramaniam et al., a solution comprising a solvent and a solute is sprayed out of a nozzle in the form of atomized droplets into a supercritical antisolvent, which causes depletion of the solvent in the atomized droplets and recrystallization of the solute in the form of particles. The difference between the process according to Subramaniam et al. and conventional supercritical anti-solvent processes is that Subramaniam et al. teaches that the solution should be introduced into the nozzle together with an "energizing gas" (which Subramaniam et al. also refers to as a "compressed fluid" or "compressed gas" - see col. 8, lines 9-10) that exits the nozzle at a velocity such that the spray of solution is "shattered into extremely small droplets at the nozzle exit" (col. 6, lines 1-8). Subramaniam et al. teaches that "[c]ontact between the extremely small spray droplets and a turbulent stream of virtually pure antisolvent results in high solvent depletion rates, i.e. high mass transfer rates, and low probability for droplet coalescence" (col. 6, lines 13-18).

In contrast to the method and apparatus according to Subramaniam et al., the invention as claimed in the present application requires that a growth retardant compound that is at least partially soluble in the SCF and includes at least one functional group or portion that is SCF-philic and at least one functional group or portion that is SCF-phobic or solute material-philic to be:

(1) present in the solution that is sprayed into the SCF, as claimed in claims 1-7; or

(2) dissolved in the SCF into which the solution is sprayed, as claimed in claims 8-14; or

(3) dissolved in the SCF together with a solute that is sprayed across the pressure drop, as claimed in claims 15-21.

The growth retardant compound protects or shields the developing particle nuclei precipitated upon depletion of the solvent thereby preventing the particles from agglomerating into larger particles. Applicants' mechanism for obtaining small particles is thus a chemical mechanism as opposed to a physical mechanism such as used in Subramaniam et al.

Subramaniam et al. does mention trifluoromethane (which is a "fluorocarbon"), but only in the context of trifluoromethane being used as a supercritical anti-solvent. Subramaniam et al. does not teach the use of trifluoromethan or any other fluorocarbon as a growth retardant compound present in a solution that is sprayed into a SCF, as claimed in claims 1-7; as a growth retardant compound dissolved in a SCF into which a solution is sprayed, as claimed in claims 8-14; or as a growth retardant compound that is dissolved in a SCF together with a solute that is sprayed across a pressure drop, as claimed in claims 15-21.

Clearly, the process according to Subramaniam et al. is substantially different than the process claimed in the present application. The rejection of claims 1-3, 5-10, 12-17 and 19-21 under 35 U.S.C. §102(b) as being anticipated by Subramaniam et al. is clearly improper. Reconsideration is respectfully requested.

Claim Rejections - 35 USC §103

Also in the prior Office Action, the Examiner rejected claims 1-21 under 35 U.S.C. §103(a) as being unpatenable over Subramaniam et al. in view of Tarara et al., U.S. Pat. App. Publ. No. US 2003/0064029 A1. The Examiner contends that Subramaniam et al. is deficient in disclosing that the growth retardant compound can be a sugar acetate, fluorocarbon or a block polymer. This is certainly true. As noted above, Subramaniam et al. is deficient in teaching the use of any growth retardant compounds of any kind. Subramaniam et al. achieves small particle size in a

supercritical anti-solvent process through the use of an "energizing gas" that physically creates an ultrasonic or near-sonic wave front at the nozzle tip that breaks an atomized spray of solution into small particles. Subramaniam et al. does not achieve small particle size through the use of chemical growth retardant compounds of any type.

Tarara et al. cannot be relied upon to overcome the deficiencies in the teachings of Subramaniam et al. as applied to the present claims. Tarara et al. is directed to the formation of "perforated microstructures" that can be used for inhaled drug therapy. The "perforated microstructures" according to Tarara et al. are formed via a spray drying process that employs a "blowing agent" and uses "commercially available equipment" (paragraph [0025]).

Tarara et al. teaches that in some applications it is desirable to retain high amounts of the "blowing agent" in the spray-dried product (see paragraphs [0087] and [0088]). In order to retain the "blowing agent" in the "perforated microstructures", Tarara et al. teaches that the outlet temperature of the spray drying device should be about 20°C to about 150°C below the boiling point of the "blowing agent" (see paragraph [0088]). It is in this context that Tarara et al. mentions that "[i]n some cases, the temperature differential can be outside this range such as, for example, when producing the particulates under supercritical conditions or using lyophilization techniques" (paragraph [0088]). This is the only instance in Tarara et al. where the word "supercritical" is mentioned. It is inconceivable how one of ordinary skill in the art, in view of Tarara et al. taken as a whole, would be motivated to modify the process according to Subramaniam et al. to incorporate a growth retardant compound such that it is:

(1) present in the solution that is sprayed into the SCF, as claimed in claims 1-7; or

(2) dissolved in the SCF into which the solution is sprayed, as claimed in claims 8-14; or

(3) dissolved in the SCF together with a solute that is sprayed across the pressure drop, as claimed in claims 15-21.

Clearly, Tarara et al. cannot be combined with Subramaniam et al. to read on applicants' claims. Reconsideration of the rejection of claims 1-21 is thus respectfully requested.

Double Patenting

Claims 1-21 were also provisionally rejected on obviousness-type double patenting grounds as being unpatentable over claims 1, 9-13, 15 and 16 of copending Application Ser. No. 10/534,665, and claims 1-6, 9-12, 14 and 15 of copending Application Ser. No. 10/789,422. Applicants do not agree that the present claims should have been provisionally rejected on obviousness-type double patenting grounds, but have submitted properly executed Terminal Disclaimers to obviate the provisional rejections.

Conclusion

In light of the foregoing, it is respectfully submitted that the present application is in a condition for allowance and notice to that effect is hereby requested. If it is determined that the application is not in a condition for allowance, the Examiner is invited to initiate a telephone interview with the undersigned attorney to expedite prosecution of the present application.

If there are any additional fees resulting from this communication, please charge the same to our Deposit Account No. 18-0160, our Order No. QIA-14368.

Respectfully submitted,

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